

Graspit™ Nitinol Stone Retrieval Forceps

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Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Intended Use/Indications for Use

The Graspit Nitinol Stone Retrieval Forceps are used endoscopically to entrap and remove stones from the urinary tract.

Contraindications

None known.

Warnings

- Some stones may be too large to be removed endoscopically with stone retrieval forceps. To avoid stone impaction, fluoroscopy or x-ray should be used to determine the size of the stone; do not use the Graspit Nitinol Stone Retrieval Forceps if the stone is too large to be removed endoscopically or held in the forceps.
- Do not rotate open forceps in ureter.
- This device must not come in contact with any electrified instrument.
- This device should not be directly fired upon by a laser.

Adverse Events

Adverse events generally recognized with the use of stone retrieval devices include, but are not limited to:

- Perforation
- Evulsion
- Hemorrhage
- Edema

Precaution: Before using, inspect the product pouch for any breach of the package to ensure a sterile product and inspect product for any damage. If seal has been broken or product is damaged DO NOT USE, immediately return package and product to Boston Scientific.

Precaution: Kinks in the sheath will hinder the mechanical operation of the forceps.

Precaution: It is recommended that the ureter be predilated before endoscopy and stone retrieval to prevent stone impaction when extracting the stone.

Caution: If resistance is encountered while attempting to withdraw the forceps into the sheath or the sheath through the scope, DO NOT EXERT EXCESSIVE FORCE.

Precaution: Some stones may be too large to withdraw the forceps and stone fully into the sheath. Do not exert excessive force to withdraw forceps and stone into sheath. Carefully maintain forceps position to hold the stone in place.